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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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AKIN GUMP STRAUSS HAUER & FELD L.L.P.  
ONE COMMERCE SQUARE  
2005 MARKET STREET, SUITE 2200  
PHILADELPHIA, PA 19103-7013

EXAMINER

OLSEN, KAJ K

ART UNIT PAPER NUMBER

1753

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/800,014

Applicant(s)

GEPHART ET AL.

Examiner

Kaj K Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18, 21, 24-34 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 21, 24-34 and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-18, 21, 24-34 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 has been amended with limitations drawn to the presence of a unique identification code for the instrument. Although the examiner appreciates that there is support for the code itself (in particular paragraph 041), the wording of the new claim language would appear to be stating something that the original disclosure does not support. In particular, claim 1 now states that the instrument includes “a unique identification code *to provide positive identification of all test results* obtained using the instrument” (emphasis added). This claim language appears to be stating that the identification code itself is providing some function that paragraph 041 does not appear to support. Paragraph 041 states that a unique identification code is present and doesn’t appear to imply that the code does anything other than uniquely identify the instrument. Moreover, the examiner is confused as to what the “positive identification of all test results” even means. The examiner understands the concept of uniquely identifying the instrument itself (e.g. a serial number), but how is a test result positively identified? Does this mean the identification code is stored with each data file? Furthermore, how is this term

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supported by the original disclosure? Paragraph 041 only discusses a positive identification of the instrument itself and that instrument itself then provided the test result (see p. 11, lines 18 and 19). That would not appear to constitute a “positive identification of all test results” because there is no set forth nexus in the original disclosure between uniquely identifying the instrument and uniquely identifying the test results. Clarification is requested.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-18, 21, 24-34 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In addition to the fact that the examiner is unclear whether this new claim language is supported by the original disclosure, the examiner was also unclear what “positive identification of all test results” was even referring to (see discussion above). This confusion renders the claims indefinite as well.

### ***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-12, 17, 18, 21, 24, 26-28, 30 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks (USP 5,096,669) in view of Patko et al (USP 6,153,085) and Smith (USP 5,108,889). Smith is being cited for the first time with this office action. Its use here was necessitated by the amendment to the claims.

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7. Lauks disclosed all the limitations of the set forth system (see rejection of 9-11-2003), but did not explicitly set forth an indicia unique for each test cell, nor did Lauks set forth a reader for the indicia. Patko teaches in an alternate electrochemical sensor that a barcode can be utilized for storing information about the electrochemical device and that each barcode should be unique for that electrochemical sensor (col. 10, lines 48-56). The barcode of Patko allows more information to be transmitted to the instrument than can be transmitted by the notches of Lauks including calibration and quality control information and whether the sensor has been previously inserted into the instrument (col. 10, lines 48-56). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Patko for the system of Lauks in order to transmit more information about the test cell to the instrument including whether the strip has been previously inserted into the sensor. This is particular relevant to the teaching of Lauks, which is drawn to a sensor that is meant to be utilized once and discarded (see the title and the last sentence of the abstract). Preventing the reuse of the test strip would potentially prevent a false analysis of a patient's blood.

8. Applicant has amended claim 1 to set forth the presence of a unique identification code for the electronic instrument. However, this claimed identification code would read on the well established practice of having a serial number associated with an instrument. Smith teaches the presence of such a serial number for its instrument. See col. 52, line 66 through col. 53, line 8 and col. 56, lines 57-65. Having a serial number be associated with the instruments allows the instrument to be uniquely identified for inventory, tracking and customization purposes. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Smith for the system of Lauks and Patko in order to better track

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and inventory the instrument. With respect to the claim language “to provide positive identification of all test results obtained using the instrument”, it is unclear to the examiner what this claim language it particularly trying to specify (see 112 rejections above). However, regardless of what this language is attempting to recite, it would appear to constitute the intended use of the unique identification code and the intended use need not be given further due consideration in determining patentability of an apparatus.

9. Alternatively, even if the examiner presumes this new claim language is referring to storing the identification code with each data file (as postulated by the examiner above) and this limitation is construed as being explicitly providing this function, storing the instruments identification code with each data file would have been obvious. In particular, Lauks teaches that the instrument should have the capability of outputting the data such that it can be stored and/or further processed. See col. 10, lines 35-44. Smith teaches that each instrument can have customized characteristics including units of operation and look-up tables. See col. 52, line 66 through col. 53, line 8 and col. 56, lines 57-65. If each instrument is customized, then it would have been obvious to have information about the instrument that prepared the data stored with the data files such that when the data is either further processed or reexamined at a latter time, the operator analyzing the data would be able to determine both when and where the data was taken as well as appropriately account for any customization.

10. With respect to the various dependent claims, see the rejection of 9-11-2003.

11. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks, Patko and Smith in further view of Tomita (USP 4,797,188).

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12. Lauks, Patko and Smith teach all the limitations of the claims, but do not explicitly provide the detailed structure for the test cell. Tomita teaches in an alternate cell for monitoring the constituents in aqueous samples that a typical test cell for measuring concentrations of things such as potassium includes an electrolyte (i.e. an internal solution) 19 coated over one of the electrodes (fig. 1). Internal solutions are a well established means for ensuring appropriate electrochemical contact between the metal electrode and the sample and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Tomita for the system of Lauks, Patko and Smith in order to ensure appropriate electrochemical contact between the metal electrode and the sample. Tomita also teaches the use of a gelled form of the internal solution as well as an ion selective membrane 20 which has been impregnated with an appropriate chemical species over that gelled solution (col. 4, line 62 through col. 5, line 38).

13. Claims 25 and 29 (and claims 27 and 28 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks, Patko and Smith in further view of Jakubowicz et al (USP 4,798,705).

14. Lauks, Patko and Smith set forth all the limitations of the claims, but did not explicitly set forth the use of either a liquid crystal display or a thermal printer. Jakubowicz discloses that both those forms displays and printers are well known in the analytical art (col. 3, lines 3-6). With respect to claims 27 and 28 in the alternative), Jakubowicz also shows that the printer and keyboard of a system can be integrated into the instrument (fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks, Patko and Smith because the substitution of one known

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means for display or printer for another known means requires only routine skill in the art.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks, Patko and Smith because integrating the keyboard and printer into the single device simplifies the system making it easier to handle.

15. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks, Patko and Smith in further view of Betts et al (USP 5,405,510).

16. Lauks, Patko and Smith set forth all the limitations of the claims, but did not explicitly identify the use of the RS 232 interface or the use of an internal power source. Betts discloses that both that particular interface as well as the use of batteries is well known in the art (col. 14, lines 6-9 and col. 19, lines 15-18). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Betts for the system of Lauks, Patko and Smith because the use of standard interfaces and power sources requires only routine skill in the art. With respect to the batteries being rechargeable, rechargeable batteries are an obvious and conventional form of battery and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize them because they would save the system operator money over the long term.

### ***Response to Arguments***

17. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.



***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj K Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753  
February 7, 2005



**KAJ K. OLSEN**  
**PRIMARY EXAMINER**